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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,432	07/20/2001	Jacob Waugh	13720-105065US1	2657

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
05/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	09/910,432	WAUGH ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-85,87-90,139 and 140* is/are pending in the application.

4a) Of the above claim(s) *42-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,41,87-90,139 and 140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/08 has been entered.

Claims 40-85, 87-90, 139 and 140 (as renumbered in the Examiner's amendment of 3/13/08) are pending.

After further consideration, the indication of allowability of claims 40-85, 87-90, 139 and 140 is withdrawn.

Election/Restrictions

Claims 40, 87-89, and 139 are generic to the patentably distinct species of therapeutic agents disclosed in claims 41-85, 90, and 140. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

During a telephone conversation with Joseph Eng on 5/8/2008 a provisional election was made without traverse to prosecute the invention of botulinum toxin, readable on claims 40, 41, 87-90, 139, and 140. Affirmation of this election must be made by applicant in replying to this Office action. Claims 42-85 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 40, 41, 87-90, 139, and 140 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40, 41, 139, and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayyem et al (WO 96/11712) in view of Yan et al (US 7,008,924) and Foster et al (US 5,989,545).

Kayyem taught cell-specific delivery vehicles comprising a oppositely charged polymers. In one embodiment of the invention, a delivery vehicle is provided comprising a) a first polymeric molecule having a net positive or negative charge, b) at least one second polymeric molecule having a net charge opposite that of the first polymeric molecule and complexed with the first polymeric molecule, the second polymeric molecule having attached thereto at least one cell targeting moiety, and c) at least one physiological agent attached to the first or second polymeric molecule (see Figs. 1 A and 1 B) or to a third polymeric molecule (see Fig. 1 C), wherein the third polymeric molecule, if present, has a net charge opposite that of the first polymeric molecule and is complexed with the first polymeric molecule. See abstract; Fig. 1C; page 5, lines 3-11; and page 17, lines 5-17. The physiological agent could be a therapeutic agent that has a physiological effect on the cell to which it is delivered. See page 14, lines 20-22. Fusogenic peptides, and peptides that facilitate translocation between intracellular compartments may be attached to the polymers. See page 23, lines 15-27.

Thus Kayyem fairly taught a composition comprising a cationic polymer complexed to a plurality of anionic polymers wherein the anionic polymers comprised attached targeting agents and therapeutic agents. The compositions can also comprise a fusogenic peptides or nuclear localization peptides.

Kayyem did not teach composition wherein a cationic polymer covalently attached to a plurality of amino acid sequences of SEQ ID NO: 20, or the use of botulinum toxin as a therapeutic agent.

Yan taught conjugates comprising peptides of the sequence YGRKKRRQRRR or GGGGYGRKKRRQRRR. See; column 35, lines 22-33. Yan taught that such Tat peptides were peptide transduction domains that facilitated internalization of attached molecules into a cell. See column 35, lines 22-55.

Foster taught that botulinum toxin was useful as a therapeutic agent, and that it could be covalently linked to a targeting ligand. See abstract; and e.g. claims 1-11.

It would have been obvious to one of ordinary skill in the art at the time of the invention to attach a peptide of SEQ ID NO: 20 to the cationic polymer of Kayyem in order to facilitate cellular uptake of the complex. One would have been motivated to attach the peptide to the cationic polymer because the peptide is strongly cationic, and the invention of Kayyem depends on the interaction of oppositely charged polymers to form a complex. Accordingly, one of ordinary skill when deciding which polymer to attach the peptide to, would opt to place it on the like-charged cationic polymer in order to avoid interfering with the charge interaction between the cationic and anionic polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use botulinum toxin as a therapeutic agent in the invention of Kayyem because it is readily apparent that the composition of Kayyem is useful for delivery of therapeutic agents generally to cells, because botulinum toxin was a well recognized

therapeutic agent, as evidenced by Foster, and because Foster showed that botulinum toxin could be conjugated to targeting agents without loss of activity. Thus the invention as a whole was prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40, 41, 87-90, 139, and 140 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-, 10-24, 30, 31, 33-50, 57, and 59-61 of copending Application No. 10/591,486. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The '486 application claims compositions comprising a biologically active protein and a carrier which comprises polymeric backbone having attached positively charged branching groups and which is present in an effective amount for transdermal delivery, wherein the association between the carrier and the biologically active protein is non-covalent. The polymeric backbone may comprise instant SEQ ID NO: 19 or 20 (see claim 31). It is clear from the supporting specification that these compositions may contain negatively charged polymers comprising botulinum toxin and targeting agents. Thus invention as a whole was prima facie obvious.

Claims 40, 41, 87-90, 139, and 140 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 10-24, 30, 31, 33-50, 57, 59-61, and 63-66 of copending Application No. 11/073,307. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The '307 application claims compositions comprising a biologically active protein and a carrier which comprises polymeric backbone having attached positively charged branching groups and which is present in an effective amount for transdermal delivery, wherein the association between the carrier and the biologically active protein is non-covalent. The polymeric backbone may comprise instant SEQ ID NO: 19 or 20 (see claim 31). It is clear from the supporting specification that these compositions may contain negatively charged polymers comprising botulinum toxin and targeting agents. Thus invention as a whole was prima facie obvious.

Conclusion

No claim is allowed. Embodiments of the invention requiring SEQ ID NO: 19 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, James (Doug) Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Richard Schnizer, Ph. D./
Primary Examiner, Art Unit 1635